REMARKS

Claims 12-26 are pending in the application; each of the claims has been rejected.

I. Claim Rejections Under 35 U.S.C. §103

A. At page 3 of the office action, claims 12-16 and 20-26 are rejected as being obvious under 35 U.S.C. §103(a) over Kaur et al. (*Eur. J. Pharma. Sci.*, 2002) in view of Kruszewskya et al. (*Microecol. Ther.*, 2002) and Naito et al. (*Free Radical Biol. Med.*, 2002).

Applicants respectfully traverse the Examiner's position and assert that the cited publications do not establish that the rejected claims are *prima facie* obvious under 35 U.S.C. §103(a) for the following reasons.

In the paragraph bridging pages 11 and 12 of the office action, the Examiner invites Applicants to provide evidence or arguments that the results of the claimed combination are unexpected.

In doing so, Applicants note that at page 7 of the office action the Examiner concludes:

> A person of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success in administering a formulation of the combination of probiotic strains in effective amount with fiber for treating *H. pylori* induce gastric inflammation as taught by Naito et al. in order to provide a method of treating a stress-induced inflammatory disorder because Kruszewskya et al. teach the probiotic strains, *Pediococcus pentosaceus 16: 1, Leuconostoc mesenteriodes 77: 1, lactobacillus paracasei subsp paracasei F-19, and Lactobacillus plantarum 2592*, produce bacteriocins with bactericidal effect against bacterial species like *H. pylori*.

Applicants respectfully disagree with this conclusion.

According to the Examiner, Kruszewska discloses that the strains in concern produce bacteriocins with bactericidal effect against bacterial species like *H. pylori*. The

only conclusion that possibly may be drawn from this teaching is that an *H. pylori* infection may be treated by use of the strains taught by Kruszewska.

However, claim 12 is not concerned with the treatment of bacterial infections, but with the treatment of stress induced inflammatory disorders, such as stomach inflammation.

As is evident from paragraph [0021] of US 2007/0286916, the present invention is directed to the reduction and/or elimination of the influences of the negative changes of acute phase reaction and chronic phase reaction, which makes it possible to treat stress-induced inflammatory disorders. Accordingly, the present invention is directed to the treatment of one of the symptoms, i.e. the inflammatory response, resulting from an infection by *H. pylori* rather than being directed to the treatment of the infection itself.

No conclusion with regard to the possible effects exerted by the strains taught by Kruszewska on an inflammatory response caused by a *H. pylori* infection may be drawn from the fact that the strains produce bacteriocins. A treatment directed to just the cause of the inflammation will have no or very little effect on the inflammation itself, once established.

As a comparison, it is noted that peptic ulcers caused by a *H. pylori* infection are typically treated with a combination of an antibiotic (e.g., Clarithromycin, Amoxicillin, Tetracycline, Metronidazole) and a proton pump inhibitor (e.g. omeprazole).

While Kruszewska states that the analyses presented are important, but not exclusive, for the selection of probiotic microorganisms (see page 45, right column, last paragraph), nothing is stated about their relevance for the selection of strains useful to treat stress induced inflammatory disorders. Furthermore, nothing is stated with regard to any synergistic effect resulting from a combination of two or more strains.

Accordingly, the results of the claimed combination indeed are unexpected in view of the teaching of Kauer, Kruszewska and Naito, even if combined.

Furthermore, it is noted that Naito discuss the effect of IL-8 and its role with regard to inflammation. From this teaching it is evident that the skilled person not would consider using a bacterial strain, e.g., *L. paracassei F19*, exerting a mild immunostimulatory effect, to treat a stress induced inflammatory disorder.

It is thus respectfully requested that the Examiner reconsider and withdraw the present rejection.

B. At page 8 of the office action, claims 12 and 17-19 are rejected as being obvious under 35 U.S.C. §103(a) over Kaur et al. (*Eur. J. Pharma. Sci*., 2002) in view of Kruszewskya et al. (*Microecol. Ther.*, 2002), Gibson et al. (*J. Nutr.*, 1999) and Charalampopoulos et al. (*Intl. J. Food. Microbiol.*, 2002).

Applicants respectfully traverse the Examiner's position and assert that the cited publications do not establish that the rejected claims are *prima facie* obvious under 35 U.S.C. §103(a) for the following reasons.

As in the first rejection, the Examiner bases the rejection on the disclosure of Naito, whereby the Examiner states "Kruszewskya et al. teach the strains produce bacteriocins with bactericidal effect against bacterial species like *H. pylori* (p. 44 1st column 3rd paragraph lines 1-4) (It must be noted that *H. pylori* induced infection is a stress-induced disorder)."

In response, Applicants reference their arguments above with regard to the first rejection as such arguments apply equally well to the present rejection.

In view thereof, Applicants respectfully assert that the claimed method is non-obvious over Kaur et al. in view of Kruszewskya et al., Gibson et al. and Charalampopoulos et al.

II. Conclusion

In view of the above remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the

prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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